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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/964,120	09/25/2001	Marvin L. Schilling	BWS-00-07	9970

7590 05/14/2003
BERND W. SANDT
900 Deerfield Court
Midland, MI 48640

EXAMINER

GOLLAMUDI, SHARMILA S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 05/14/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/964,120

Applicant(s)

SCHILLING ET AL.

Examiner

Sharmila S. Gollamudi

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-- **Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --**
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status of Application

Prosecution is re-opened in this application. The delay in making the new grounds of rejection is regretted. Applicant may re-instate the appeal by providing a supplemental brief addressing the grounds of rejection.

Claims 1-17 are pending in the prosecution of this application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.

“An organic substance that contains sufficient water causing it to be subjected to deterioration” is critical or essential to the practice of the invention. This limitation is not included in the claim(s) and the specification does not teach how to practice the invention without it. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). The scope of claims is broader than the disclosure in the instant specification. The examiner points to page 5, lines 1-16 and examples that require that the substance have a sufficient amount of water. The claims recite a method that is applied to any organic substance without regard to the amount of water. The process of dehydration requires a substance having initial water content, which claims do not recite.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite. Claim 1 recites, "recovering (a product) the biologically active components of the particulate form in (its) original form." It is unclear what exactly is recovered or how it is recovered. Is the product recovered or the biologically active component? If the latter is true, then is the active component recovered from the organic substance, particulate form, or the residue of the boiled mixture? In context of the active component, are all the biologically active components of the organic substance recovered since organic substances may contain many active components or is a specific component being recovered? The examiner points out that the applicant uses the term "substance" and "biologically active" interchangeably. For instance, in claim 6, applicant calls the substance "protein." Then what is the biologically active component that is recovered from this substance? Additionally, how can a product be recovered in its original natural structure if it has been subjected to dehydration and the method steps recited in claim 1? Lastly, how is the active recovered from the product? Is it extracted or eluted out? In regards to the applicant's arguments that the product is not extracted out, the examiner points to claim 15. Claim 15 recites an aqueous solution containing a salt and an antimicrobial agent, and natural substance which results in a particulate form. How is the particulate form recovered without extracting the liquid out? Clarification is requested. Further, in regards to both

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claim 1 and claim 3, is the mixture heated into particulate form or is the mixture already in particulate form when it is heated? Lastly, is the 15% recited in regards to the organic substance or the ionizable salt?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4, 8, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 59-088065 in view of Ueno et al (4789497).

JP teaches preparation of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document.

JP does not teach the use of NaCl or KCl in the solution.

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Ueno et al teach the process of dehydration of fish meat. Ueno teaches dehydration removes extra water and the well-known method of dehydration using sodium chloride, magnesium chloride, or calcium chloride at the time of washing. This addition promotes the bonding of proteins with Na, Mg, or Ca ions resulting in reduction in the charge of proteins and eases dehydration. Ueno et al teaches the object of washing is to remove factors that cause denaturation of proteins (col. 1, line 16 and lines 44-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use NaCl or KCl in JP's washing method before dehydrating the product method of dehydration since Ueno teaches the state of the art in regards to dehydration. One would be motivated to add the salts to facilitate dehydration and prevent denaturation of the protein. Further one would be motivated to combine both the salts and antimicrobials in the washing method prior to drying the product since both methods are geared towards preserving the proteins in the product.

Claims 3, 4-5, 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 2114865 in view of Maret (3,878,197).

GB 2114865 teaches process for drying aromatic plants. The method is applied to any plant or herb. The comminuted plant is dried in the presence of a carrier (batch mixture) such as an electrolyte, preferably sodium chloride (30%). See page 1, lines 94-120. The mixture is then vacuumed dried at a temperature not to exceed 60 degrees Celsius to a water content of 2-3%. See page 2, lines 115-120.

GB does not teach using an antimicrobial agent.

Maret teaches a process of preparing aloe vera. The process includes rinsing the leaves with chlorine solution to sterilize the leaves and aseptically dried. See column 2, lines 16-30.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use an antimicrobial agent in the batch mixture of GB. One would be motivated to do so since Maret teaches this process yields a sterile product.

Claim 1-4, 6-8, 12-14, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ries (4,066,083) in view of Puppolo (5,562,535).

Ries teaches a method of producing sterile collagen product. The starting material used for preparing the collagen can be from the skin, tendons, or bone of slaughtered animals. The tissue is then finely comminuted and added to a solution of sodium chloride (5-15%) and sodium azide (antimicrobial). The reference teaches the use of the solution allows for the removal of undesired water-soluble ballast substances and greasy components. See column 2, lines 15-35. The obtained tissue is then treated with proteolytic enzymes which do not attack the basic structure of collagen to remove the non-collagen type protein, purifying the crude collagen and then freeze-drying it (one method of dehydration) (Note example 4). The product is used for medical purposes.

Ries does not specify the method of dehydration via heating the product. Further, Ries does not specify the moisture content of the product.

Puppolo teaches a method of producing dehydrated shark cartilage. The reference teaches that prior art methods of dehydrating such as convection ovens,

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vacuum ovens, and freeze drying techniques use temperatures that are high enough to cause the loss of proteins (column 1, lines 5-16). After the undesirable components are removed from the cartilage via solvent extraction, the removal of all water and solvent is accomplished by drying the product in a sonic chamber at 85 degrees Fahrenheit or lower (col. 2, lines 34-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use heat dehydration with instant temperature. One would be motivated to do so since Puppola teaches heat drying at instant temperature preserves active components in the cartilage whereas method such as freeze drying do not.

Claim 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ries (4,066,083) in view of Puppola (5,562,535) in further view of JP 59-088065.

As set forth above, Ries teaches a method of producing sterile collagen product. The starting material used for preparing the collagen can be from the skin, tendons, or bone of slaughtered animals. The tissue is then finely comminuted and added to a solution of sodium chloride (5-15%) and sodium azide (antimicrobial). The reference teaches the use of the solution allows for the removal of undesired water-soluble ballast substances and greasy components. See column 2, lines 15-35. The obtained tissue is then treated with proteolytic enzymes which do not attack the basic structure of collagen to remove the non-collagen type protein, purifying the crude collagen and then freeze-drying it (one method of dehydration) (Note example 4). The product is used for medical purposes.

Puppol teaches a method of producing dehydrated shark cartilage at a temperature of 85 degrees Fahrenheit.

The references do not teach the use of lecithin in the mixture or hypochlorite.

JP teaches preparation of edible bone and marrow. The method includes soaking, disinfecting, and washing the edible parts in sodium hypochlorite for one hour. The parts are ground and mixed with soy lecithin at a temperature that does not degrade the protein. See page 2 of translated document. JP teaches lecithin to remove allows the easy removal of fat and blood during washing from the natural substance. See page 2, last paragraph.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add lecithin into the mixture of Ries. One would be motivated to do so since lecithin allows for the easy removal of fats as taught by JP. Further since Ries teaches that the NaCl and antimicrobial solution allows for the removal of undesirable substances and greasy components, the addition of lecithin in the mixture would cause for an additive effect.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is (703) 305-2147. The examiner can normally be reached on M-F (7:30-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on (703) 308-4628. The fax phone numbers for

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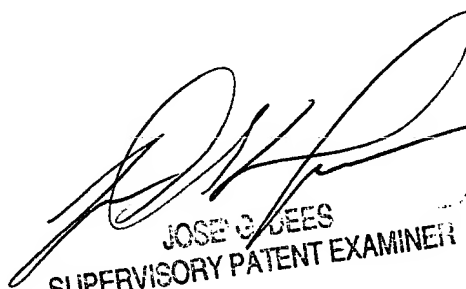
the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SSG



May 13, 2003



JOSE G. DEES
SUPERVISORY PATENT EXAMINER
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